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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,690	01/09/2001	Orville G. Kolterman	030639.0066.UTL	4666
28381	7590	04/20/2004	EXAMINER	
ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/756,690

Applicant(s)

KOLTERMAN ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 24-41 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 and 38-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 24-37 and 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 and 24-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED OFFICE ACTION

Applicant's amendment filed on 19 March 2004 is acknowledged and entered. Following the amendment, claims 19-23 are canceled, and claims 1 and 10 are amended.

Currently, claims 1-18 and 24-41 are pending, and claims 1-15, 24-37 and 41 are under consideration.

The finality of the rejection of the last Office action is withdrawn. New grounds of rejection are set forth below.

Withdrawal of Objections and Rejections:

The prior art rejection of claims 1, 3, 5, 6, 9-14, 19, 20, 24, 26, 28, 29, 32-36 and 41 under 35 U.S.C. 102(b) as being anticipated by Beeley et al. (WO 98/30231) is withdrawn in view of applicant's amendment.

The prior art rejection of claims 2, 4, 7, 8, 25, 27, 30 and 31 under 35 U.S.C. 103(a) as being unpatentable over Beeley et al. (WO 98/30231) is withdrawn in view of applicant's amendment.

The prior art rejection of claims 15 and 37 under 35 U.S.C. 103(a) as being unpatentable over Beeley et al. (WO 98/30231), and further in view of Wagle et al., US 6,326,396 B1, is withdrawn in view of applicant's amendment.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 24-37 and 41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

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one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is “undue” include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The present claims are directed to a method for lowering triglyceride levels in a subject. Claims 1, 10 and 24 recite the method steps as “identifying a subject having elevated *postprandial* triglyceride levels; and administering ...”. However, the specification does not support such limitation, and teaches otherwise. The specification teaches that “triglyceride levels vary from day to day and in response to meals, and these measurements should be made *after an overnight food and alcohol fast*” (page 2, lines 3-4 from the bottom), and that “based on measurement of *fasting* plasma triglyceride levels, triglyceride levels have been characterized” (page 4, lines 1-2). The specification does not teach to measure postprandial triglyceride levels, and to use such as an indicator for any diagnostic purpose, nor any working example suggesting the same. Further, it is well known in the prior art that triglyceride levels vary in response to meals. As such, the subjects identified and treated by the presently claimed method would include *healthy individuals* who happened to have a fatty meal, and would have normal triglyceride levels otherwise. Therefore, the method of the invention does not distinguish healthy subjects who are having transiently elevated triglyceride levels associated with food intake, and would not need any medical intervention to lower the triglyceride levels from those who have pathologically elevated triglyceride levels associated with a disease or a disorder. Thus, the claimed method is not enabled as one of skilled in the art would not know how to identify a subject in need of the treatment, and undue experimentation would be required prior to practice the claimed invention.

Due to the large quantity of experimentation necessary to identify a subject in need of lowering the elevated triglyceride levels among those having elevated postprandial triglyceride levels, the absence of instruction/guidance or working example indicating that postprandial triglyceride levels are sufficient for identifying such a subject in need of the treatment, the

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teachings of the specification supporting the opposite, the state of the prior art has established that triglyceride levels vary in response to meals, hence postprandial triglyceride levels would not be suitable as an indicator for identifying a subject in need of lowering triglyceride levels, i.e., lack of predictability, undue experimentation would be required of the skilled artisan to use the claimed invention.

Conclusion:

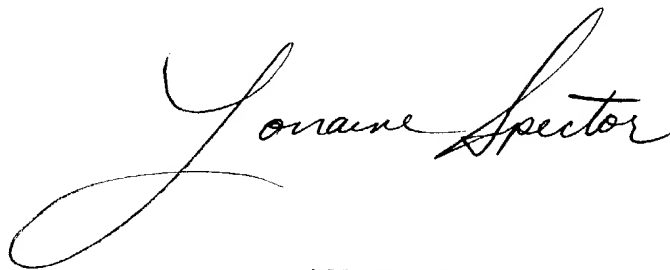
No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is fluid and elegant, with a large initial "L" and a long, sweeping underline.

**LORRAINE SPECTOR
PRIMARY EXAMINER**

Dong Jiang, Ph.D.
Patent Examiner
AU1646
4/14/04